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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/505,598	02/16/2000	Arnold M. Escano	ENDOV-48232	6592

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EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/505,598

Applicant(s)

ESCANO ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 7, 2002 has been entered as Paper # 6.

Drawings

2. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 23, 25-36, and 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 23 recites the limitation "the releaser wire" in line 2. There is insufficient antecedent basis for this limitation in the claim.

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b. Regarding independent claim 25, the newly added claim limitation “wherein one or more of the first and second release wires themselves operate to maintain an anchoring mechanism in an unexpanded condition” (see lines 14-15) is vague and indefinite:

(i) First, there are only two release wires claimed in claim 25. The phrase “one or more” gives the impression that there are more than two release wires.

(ii) Second, the phrase “themselves operate” is confusing and renders the claim vague and indefinite.

(iii) Third, the phrase “to maintain an anchoring mechanism in an unexpanded condition” is vague and renders the claim vague and indefinite since it is not specific as to which of the three anchoring mechanisms it is referring to.

c. Regarding independent claim 38, the newly added claim limitation “configuring one or more of the first and second release wires themselves to maintain an anchoring mechanism in an unexpanded condition” (see lines 13-14) is vague and indefinite:

(i) First, there are only two release wires claimed in claim 38. The phrase “one or more” gives the impression that there are more than two release wires.

(ii) Second, the phrase “configuring one or more of the first and second release wires themselves” is confusing and renders the claim vague and indefinite.

(iii) Third, the phrase “to maintain an anchoring mechanism in an unexpanded condition” is vague and renders the claim vague and indefinite since it is not specific as to which of the three anchoring mechanisms it is referring to.

d. Claim 39 recites the limitation “the third pullwire” in lines 7-8. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 25-36 and 38-40 are rejected, as best understood, under 35 U.S.C. 102(b) as being clearly anticipated by Quiachon et al. (US 5,628,783). Quiachon et al. disclose an apparatus and method for intraluminally delivering or deploying a bifurcated graft proximate the abdominal aortic bifurcation. The apparatus and method meet all the limitation of claims 25-36 and 38-40 (see whole text and Figures 1-36). As seen in Figures 1, 7, and 27, the guiding tube assembly 205 comprises a release wire that is operated (= used) to control the contralateral capsule 202 in order to maintain an anchoring mechanism in an unexpanded condition and to deploy it when the contralateral tubular leg is properly positioned (see also column 20, lines 39-47).

7. Claim 37 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Quiachon et al. (US 5,628,783). Quiachon et al. disclose an apparatus and method for intraluminally delivering or deploying a bifurcated graft proximate the abdominal aortic bifurcation. The apparatus and method meet all the limitation of claim 37 (see whole text and Figures 1-36).

8. Claims 1-31, 33, and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Piplani et al. (US 5,489,295). Piplani et al. disclose an apparatus and method for intraluminally deploying a bifurcated graft 20 into a lumen formed by a wall proximate a vascular bifurcation having an aneurysm. The bifurcated graft 20 comprises main cylindrical body 112, first tubular

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leg 116, and second tubular leg 117. A main catheter or capsule catheter 26, having a diameter ranging from 6-9 mm, houses the bifurcated graft, a set of positioning mechanisms, and a set of attaching mechanisms (see Abstract; column 2, lines 7-46; column 3, lines 7-9; Figure 1). The attaching mechanisms include expandable anchor or spring attachment means 126, 127, and 163 (having hook-like vessel engaging elements 141) attached to main cylindrical body 112, to first tubular leg 116, and to second tubular leg 117 respectively (see column 5, lines 29-67; column 10, lines 21-35; Figures 4, 8, and 17). The attaching mechanisms also include a balloon catheter assembly 71 capable of expanding the expandable spring attachment means (see column 2, lines 19-34; Figures 1 and 5). The attaching mechanisms further include a stabilization wire 89 and a stabilization button 106 carried by the tubular member or catheter shaft 72 to constrict the expandable anchor in an unexpanded condition (see column 9, lines 2-10; Figure 5). The set of positioning mechanisms includes a main guidewire 91 configured as a stiffened rod (see Figure 1). The set of positioning mechanisms of second tubular leg 117 includes a guidewire 196 that could be removably attached to second tubular leg 117 (see column 10, lines 9-26; Figure 18), secondary catheters (capsule catheter 161 and balloon catheter 162) encompassing at least a portion of the second tubular leg 117, and an expandable spring mechanism 163 at least partially encompassed by the secondary catheter (see column 10, lines 9-35; Figure 6). The attaching mechanism of secondary catheter includes a stabilization button 216 carried by the tubular member 176 to constrict the expandable anchor 163 in an unexpanded condition (see column 10, lines 21-35; Figure 6).

Response to Arguments

9. Regarding 102(b) rejection over Quiachon et al., Applicant's arguments filed November 7, 2002 have been fully considered but they are not persuasive:

a. Regarding claim 37, Applicant argues that Quiachon et al. does not disclose that the main catheter has an inner diameter measuring less than seven millimeters. Examiner respectfully disagrees. Claim 37 requires, among other things, "placing the bifurcated graft within the hollow cylindrical tube having an inner diameter less than seven millimeters along its length." Column 15, lines 37-44 disclose that part of the main catheter 160 has an inner diameter less than seven millimeters (= 6.68 mm).

b. Regarding claims 25 and 38, Applicants' arguments have been considered but are moot in view of the new ground(s) of rejection.

10. Regarding 102(b) rejection over Piplani et al., Applicant's arguments filed November 7, 2002 have been fully considered but they are not persuasive:

a. Claim 1 requires, among other things, "the set of attaching mechanisms being sutured to the bifurcated graft". This newly added claim limitation is met in Figure 4, wherein the attaching mechanisms are attached to the graft by suture material 144 (see also column 4, lines 59-67; column 6, lines 1-2).

b. Regarding claim 25, Applicant argues that Piplani et al. does not disclose "one or more of the first and second release wires themselves operating to maintain an anchoring mechanism in an unexpanded condition". Examiner respectfully disagrees. From 102(b) rejection above: "The attaching mechanisms further include a stabilization wire 89 (= release wire) and a stabilization

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button 106 carried by the tubular member or catheter shaft 72 to constrict the expandable anchor in an unexpanded condition (see column 9, lines 2-10; Figure 5). The set of positioning mechanisms includes a main guidewire 91 configured as a stiffened rod (see Figure 1). The set of positioning mechanisms of second tubular leg 117 includes a guidewire 196 that could be removably attached to second tubular leg 117 (see column 10, lines 9-26; Figure 18), secondary catheters (capsule catheter 161 and balloon catheter 162) encompassing at least a portion of the second tubular leg 117, and an expandable spring mechanism 163 at least partially encompassed by the secondary catheter (see column 10, lines 9-35; Figure 6). The attaching mechanism of secondary catheter includes a stabilization button 216 carried by the tubular member 176 to constrict the expandable anchor 163 in an unexpanded condition (see column 10, lines 21-35; Figure 6)."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:00 a.m.-4:30 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

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JGB

March 26, 2003



David H. Willse
Primary Examiner